UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v. Case No. 1:24-cv-00963

RONALD E. ZYLSTRA, D.V.M., Hon.

Defendant.
_____/

COMPLAINT

The United States of America, by its counsel, Mark A. Totten, United States Assistant Attorney for the Western District of Michigan, and Whitney M. Schnurr and Andrew J. Hull, Assistant United States Attorneys, states the following as its Complaint against the Defendant:

I. INTRODUCTION

1. This is an action to recover civil penalties and obtain injunctive relief against Defendant Ronald E. Zylstra, D.V.M. ("Dr. Zylstra"), for violating numerous recordkeeping requirements under the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801–971, and its implementing regulations. Specifically, Dr. Zylstra failed to maintain accurate dispensing records (resulting in over 41,000 unaccounted-for pills), repeatedly failed to record the receipt of Schedule II controlled substances, and failed to conduct a biennial inventory.

II. JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 21 U.S.C. §§ 842(c)(1), 843(f)(2), and 882(a), and 28 U.S.C. §§ 1331, 1345, and 1355(a).

3. Venue is appropriate in this District pursuant to 21 U.S.C. § 843(f)(2) and 28 U.S.C. §§ 1391(b)(1), 1391(b)(2), and 1395(a).

III. THE PARTIES

4. Plaintiff is the United States of America.

5. Defendant Ronald E. Zylstra, D.V.M., is a resident of the State of Michigan, who, at all relevant times, owned Kentwood Veterinary Clinic, located at 601 44th Street SE, Kentwood, MI 49548, and worked as a veterinarian there. Dr. Zylstra maintains a controlled substance registration with the U.S. Drug Enforcement Administration ("DEA"), No. BZ8669460, which authorizes him to prescribe, dispense, and administer controlled substances. Dr. Zylstra also maintains separate licensure with the State of Michigan to practice as a veterinarian and handle controlled substances.

IV. LEGAL BACKGROUND

A. The Controlled Substances Act

6. The CSA creates a category of drugs, known as "controlled substances," that are subject to strict federal monitoring and regulation based on their potential for addiction and abuse. Controlled substances are categorized into five schedules based on several factors, including their abuse potential and the likelihood they will cause dependence if misused. A drug becomes a controlled substance when it is added to one of these schedules.

7. Congress established the CSA because of the risk of addiction, misuse, and other diversion of controlled substances and the inherent risk to patients and others who use these prescription drugs. Congress also tasked the DEA with enforcing laws regarding the prescribing and dispensing of controlled substances.

8. To maintain a closed system of distribution and prevent the diversion of controlled substances, the CSA regulates persons and entities that manufacture, distribute, and dispense, controlled substances, including through strict recordkeeping requirements.

9. When individuals violate these requirements, the CSA imposes civil penalties and authorizes the United States to seek injunctive relief.

B. Registration

10. The CSA and its implementing regulations require those who handle controlled substances, other than the ultimate user, to obtain a controlled substance registration from DEA. 21 U.S.C. §§ 822, 823; 21 C.F.R. § 1301. Persons or entities maintaining a controlled substance registration from DEA are referred to as "registrants."

11. In order for a veterinarian to prescribe, dispense, or administer a controlled substance, he or she must be registered with the DEA for those activities.

C. Documentation and Recordkeeping Requirements

12. Recordkeeping is critical to maintaining the closed system of distribution under the CSA and DEA's regulations.

13. As a general matter, DEA registrants must maintain a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of by the registrant. 21 U.S.C. § 827(a)(3); 21 C.F.R. § 1304.21(a).

14. The CSA and DEA's regulations contain a variety of specific recordkeeping requirements, including the following requirements applicable to practitioners who are registered to dispense controlled substances:

a. First, a practitioner registered to dispense controlled substances must maintain a complete and accurate record of each controlled substance that it dispenses. 21 U.S.C. § 827(a)(3); 21 C.F.R. § 1304.22(c).

b. Second, a practitioner registered to dispense controlled substances must conduct a biennial inventory of all controlled substances in the registrant's possession. 21

U.S.C. § 827(a)(1); 21 C.F.R. § 1304.11(c). Under this requirement, a registered dispensing practitioner must complete a new inventory of all on-hand controlled substances at least every two years.

c. Third, a practitioner registered to dispense controlled substances must maintain accurate records of receipt of all Schedule II controlled substances on a DEA Form-222. 21 U.S.C. § 828; 21 C.F.R. § 1305.17. The DEA Form-222 is a specific ordering and receipt form used for distribution of Schedule II controlled substances between lawful registrants (*e.g.*, a wholesale distributor to a doctor's office). The DEA Form-222 contains triplicate copies. When a practitioner purchases Schedule II controlled substances, the practitioner must record on Copy 3 of the DEA Form-222 received from the supplier (1) the number of containers furnished for each item and (2) the date on which the containers are received. 21 C.F.R. § 1305.13(e). The practitioner must also maintain these DEA Forms-222 for a period of two years. 21 U.S.C. § 828(c); 21 C.F.R. § 1305.17(a), (c).

15. Practitioners who violate these recordkeeping requirements are subject to civil penalties and injunctive relief. 21 U.S.C. §§ 842(a)(5), 842(c)(1)(B)(i), 843(f); 21 C.F.R. § 85.5.

V. FACTS

16. Defendant Dr. Zylstra is a veterinarian who owns and practices at Kentwood Veterinary Clinic in Kentwood, Michigan.

17. On December 20, 2023, DEA conducted an inspection of Kentwood Veterinary Clinic with the consent of Dr. Zylstra. The inspection revealed a number of recordkeeping violations.

18. First, an accountability audit revealed that Dr. Zylstra failed to maintain accurate

dispensing records for multiple controlled substances.

19. Specifically, during an accountability audit, a DEA diversion investigator attempts to reconcile the physical counts of controlled substances from the registrant's last biennial inventory with the counts on the date of the inspection. In summary, the diversion investigator begins with the biennial inventory count, adds any controlled substances subsequently received, and subtracts any controlled substances that have been dispensed, distributed, or otherwise disposed of, per the registrant's records. When all incoming and outgoing controlled substances are properly accounted for, the counts of the biennial inventory and the count on the date of the inspection should reconcile.

20. DEA's accountability audit of Dr. Zylstra revealed that, for the period of July 13, 2021 through December 20, 2023, Dr. Zylstra's records could not account for over 41,000 Schedule III and IV controlled substance pills, including pills for tramadol hydrochloride, diazepam, and acetaminophen with codeine.

21. Second, the inspection revealed that Dr. Zylstra failed to maintain records of receipt for Schedule II controlled substances.

22. Dr. Zylstra presented twenty-nine DEA Forms-222 dated between January 12, 2021 and August 4, 2023. On each of the twenty-nine forms, Dr. Zylstra failed to record the number of containers received of each Schedule II substance and the date on which it was received.

23. Third, the inspection revealed that Dr. Zylstra did not conduct a biennial inventory.

24. Dr. Zylstra presented DEA with two inventories, dated July 13, 2021 and November 3, 2023. Thus, Dr. Zylstra's most recent inventory was taken nearly four months after it was due. The inventories also failed to indicate whether they were taken at the open or close of business.

COUNT I
(Civil Penalties for Failing to Keep Records)

25. The United States repeats and realleges Paragraphs 1 through 23 as if fully set forth herein.

26. The CSA and its implementing regulations prohibited Dr. Zylstra from violating the CSA's recordkeeping requirements.

27. Dr. Zylstra violated these recordkeeping requirements by:

a. failing to maintain complete and accurate controlled substance dispensing records, in violation of 21 U.S.C. §§ 827(a)(3), 842(a)(5), and 21 C.F.R. § 1304.22;

b. failing to conduct a biennial inventory, in violation of 21 U.S.C. §§ 827(a)(1) and 21 C.F.R. §§ 1304.11; and

c. failing to maintain records of receipt of Schedule II controlled substances, in violation of 21 U.S.C. § 828 and 21 C.F.R. § 1305.13.

28. As a result, Dr. Zylstra is liable for penalties of up to $18,759 for each violation proven at trial. 21 U.S.C. §§ 842(a)(5), 842(c)(1)(B)(i); 28 C.F.R. § 85.5.

COUNT II
(Injunctive Relief)

29. The United States repeats and realleges Paragraphs 1 through 27 as if fully set forth herein.

30. As a result of the violations referred to in Count I, Dr. Zylstra is subject to injunctive relief pursuant to 21 U.S.C. §§ 843(f) and 882(a).

PRAYER FOR RELIEF

WHEREFORE, the United States demands judgment in its favor and against Dr. Zylstra as follows:

A. As to Count I, for a maximum statutory penalty of $18,759 for each violation of the CSA proven at trial pursuant to 21 U.S.C. § 842;

B. As to Count II, entry of an order:

1. Declaring that Dr. Zylstra violated the CSA, specifically 21 U.S.C. § 842(a)(5);
2. Enjoining Dr. Zylstra from directly or indirectly distributing, dispensing, delivering, administering, or prescribing any controlled substances as defined and identified in the CSA;
3. Directing Dr. Zylstra to surrender his existing certificate of registration with DEA; and
4. Enjoining Dr. Zylstra from applying or reapplying to DEA for a certificate of registration as a practitioner to prescribe, administer, and dispense any controlled substances for a period of five years.

C. For interest, attorneys' fees, and costs as allowed by law; and

D. For all such other and further relief as the Court may deem just and proper.

Dated: September 16, 2024

Respectfully submitted,

MARK A. TOTTEN
United States Attorney

/s/ Whitney M. Schnurr

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